8EHQ-1003-15451

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Degussa Corporation
379 Interpace Parkway
P.O. Box 677
Parsippany, NJ 07054-0677

Direct: (973) 541-8047
Fax: (973) 541-8040

Shaun.Clancy@degussa.com
www.degussa.com

October 6, 2003

Document Processing Center
EPA East (Mail Code 7407M)
Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

Contain NO CBI

Dear Madam or Sir:

Enclosed are summaries of 43 toxicology studies conducted by or for Degussa AG in Germany. These summaries reflect the results of one or more studies conducted on each of 21 chemical substances. Twelve of the summaries include information which we are reporting pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The remaining nine studies include information that suggests that the test substance may cause adverse health or environmental effects at high exposure levels. However, because these substances are manufactured or imported in the United States only in limited quantities for use as intermediates in chemical synthesis, they do not currently present a substantial risk to health or the environment. We are therefore submitting them to EPA on a "For Your Information" basis.

These 21 summaries are being submitted pursuant to a data review that Degussa is conducting in connection with its implementation of a new computer system that will permit Degussa Corporation in the United States to access data previously available only to Degussa AG in Germany. Recognizing that a large number of these studies might need to be reported under TSCA 8(e), Degussa proactively contacted EPA in mid 2002 and proposed to review the studies in batches and submit any 8(e) reportable data to EPA within 15 business days (now 30 calendar days) of completing its review of each batch. Degussa estimated that the review would take approximately six month to complete. In a memorandum received in November 2002, the Agency concurred in this approach.

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These studies were made available to Degussa Corporation in April 2003. Degussa's toxicologists in Germany have reviewed more than 750 studies on approximately 100 chemical substances and prepared English summaries of the results of 70 studies for evaluation by scientists in the United States for reporting under TSCA Section 8(e). This submission represents Degussa's review of this first batch of studies by our scientists in Germany and the United States, which was completed on September 12, 2003. Degussa has determined that approximately 1500 studies remain to be reviewed. As we have separately informed Ms. Ann Pontius of the Toxics and Pesticides Enforcement Division, we estimate that the review of the remaining studies will take an additional nine months to complete. We will continue to submit reportable and FYI studies to EPA as our review of subsequent batches is completed.

We appreciate your attention to this matter and request your comments regarding the approach we have taken. Please do not hesitate to call me at (973) 541-8047 if you have any questions or wish to discuss this matter further.

Best regards,

Shaun F. Clancy, Ph.D.

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Degussa Corporation

Memo

To: File

From: Shaun Clancy

CC:

Date: 10/06/03

Re: TSCA 8(e) Review – 10431-98-8

Two endpoints were provided by Fine Chemicals for 10431-98-8 2-Ethyl-2-oxazoline

- Skin Irritation
- Skin Sensitization

This chemical is used as an intermediate in organic synthesis and is not expected to be used in a way such that human exposure outside of an industrial setting will occur or that an environmental exposure will result. Appropriate Personal Protective Equipment is specified in the MSDS as is warnings not to allow the substance to be released. When used correctly the risk for human and environmental exposure is minimal.

The result of the skin irritation study is reportable under TSCA 8(e) since the effect is severe and the pH is not high enough that the result is expected. Because of the degree of sensitization induced by the chemical and the use pattern of the chemical there is little likelihood of exposure. It is concluded that this effects is probably not considered to be reportable under TSCA 8(e) and will be submitted on an FYI basis.

Contains No CBI

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Fax

To: Shaun Clancy
S-SR-US-EHS

Fax-No. Recipient: 001-973 541 8040

Pages (total): 10

cc: Dr. W. Mayr/FC-TME-CSM

Degussa AG
Rodenbacher Chaussee 4
63457 Hanau-Wolfgang
Germany

T +49-6181-59-3900
F +49-6181-59-2083

sylvia.jacobi@degussa.com

www.degussa.com

Fine chemicals
Chemicals Safety
Management

FC-TME-CSM/Dr.Jbi/sch

August, 6 2003

Initial notice of Information for possible TSCA 8e submission
2-Ethyl-2-oxazoline, CAS-No. 10431-98-8

Dear Shaun,

Please find attached data obtained for the above mentioned substance for assessment of possible TSCA reportability.

I am at your disposal for any further questions.

English translations of the summaries and/or results of the studies are attached.

Best regards

Sylvia Jacobi

degussa.

Degussa AG
Rodenbacher Chaussee 4
63457 Hanau-Wolfgang
Germany

T +49 6181 59-3900
F +49 6181 59-2083

Fine chemicals
Chemicals Safety
Management

August 6, 2003

Initial Notice of Information to be assessed for Possible TSCA, Sec. 8e Reporting

Name / Trade name of the Substance	**2-Ethyl-2-oxazoline**
CAS-No.:	**10431-98-8**

Human Health Effects [x]

Environmental Effects [ ]

Degussa-Study-No.:	94-0250-DGT 94-0252-DGT
Other Source of information:	

Summary of Adverse Effects
Acute skin irritation/corrosion study in rabbits
Source: Degussa AG, unpublished report No. 94-0250-DGT
Guideline: OECD Sect. 4 No. 404 (1981), GLP

The study was conducted using two test animals. 0.5 ml of the undiluted test substance was applied to the shaved skin of the animals. Exposure lasted either 3 minutes or 4 hours under open or semi occlusive dressing respectively. The skin was rinsed with warm water after the exposure period.
After 4 hours exposure in depth injury of the skin was observed, severe erythema, edema and necrosis. The animal was sacrificed after 24 hours for humane reasons.
After 3 min of exposure moderate to severe erythema and severe edema was observed after 1 to 72 h. The skin was brownish red and severe bleedings were observed in the subcutis. Escar and scab formation was observed from day 6 to day 20. Scar formation on day 24.
It can be concluded that the test substance revealed severe corrosive properties already after 3 min of exposure.

Skin sensitization study (Method of Bühler) in guinea pigs
Source: Degussa AG, unpublished report No. 94-0252-DGT
Guideline: OECD Sect. 4 No. 406 (1981), GLP

In a pre-test the maximum irritant and minimum non-irritant concentration of the test substance was determined.

In the main study 20 guinea pigs were used as test group, 10 as vehicle control. The first (day 0) and second induction (day 7) was performed with

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50% of the test substance in corn oil. Because of severe skin reactions in the first and second induction phase the test substance concentration was reduced to 25% in corn oil for the third induction phase. For the induction the test substance was applied by a patch to the shaved right flank of the animals and kept 6 h under occlusive conditions.

Challenge was performed on day 28 with 5% of the test substance in corn oil that was applied by a patch to the shaved left flank of the animals and kept 6 h under occlusive conditions. Skin readings were performed 24 and 48 h after removal of the patch. 11 of 20 animals of the test group showed a positive skin reaction after 24 h, 5/20 after 48 h. None of the control animals showed a positive reaction. It was concluded that the test substance is a skin sensitizer in this test system.

Nature and Extent of Risk Involved:

1. Risk of incapacitation due to severe skin corrosion already after 3 min of exposure.
2. Risk of skin sensitization depending on the exposure situation.

Under normal conditions skin protection should be applied due to the corrosive properties and skin exposure avoided.

Information by	Date:
Dr. Sylvia Jacobi	August 6, 2003

hüls	Prüfinstitut für Toxikologie 45764 Marl	Phone No.: 02365/494890

Final Report

No. HS-94/0124

Degussa-Hüls AG – REG No.
94 0252 DGT

2-Ethyl-2-oxazoline

on the Guinea Pig
(Bühler Method)

The undersigned hereby declares that the tests described in the following report were conducted under his supervision according to good laboratory practice (GLP). in accordance with Appendix 1 to the Chemical Law of March 14. 1990 (OECD – Principles of Good Laboratory Practice (GLP) of Feb. 4, 1983) and the results completely report the course of the study.

Study Director	Dr. Mürmann	[Signature]	Date July 4, 94

The final report comprises 38 pages.

Summary

The test substance 2-ethyl-2-oxazoline was tested for skin sensitization on the guinea pig by the method according to Bühler. To determine the potentially sensitizing action of 2-ethyl-2-oxazoline, 20 test animals and 10 control animals were used in the study. All reactions, particularly erythema and edema, were evaluated 30 and 54 hr after the induction treatment.

The screening test showed that the 50% test substance preparation in corn oil MEH 56 is suitable as a slightly irritant concentration for treatments in induction phases I, II and III.

For the challenge treatment, a concentration of 5% 2-ethyl-2-oxazoline in corn kernel oil MEH 56 was tested as the non-irritant test substance concentration in the fourth week of testing (animals the same age as the animals of the primary test).

During the study, no substance-induced systemic effects and no substance-induced impairment of the body weight gain was observed in the animals of the test group and control group.

The dermal treatments in induction phase I caused very slight erythema in 7 test animals 30 hr after application and clearly delineated erythema associated with very mild to prominent edema in two animals. Eleven test animals and all 10 control animals were free of symptoms of irritation. Before application (Day 7) in induction phase II, the test animals showed mild to severe scale formations, in some cases with chapped skin surface in the area of application.

The exposure in induction phase II was on intact skin. Nonetheless, 30 hr after application, skin necrosis and severe scaling on the left flank were observed in 15 test animals. The other animals had prominent to medium-grade skin irritations with scaling. The control animals showed no skin changes.

On the basis of these results, the test substance concentration was reduced to 25% in corn oil MEH 56 for induction phase III. Before application in induction phase III, all animals exhibited scabs on the treated skin, which was bloody in 16 animals. The control animals showed no skin changes.

The application of induction phase III was again done on intact skin. The evaluation of the skin 30 hr after application showed predominantly distinct skin reactions in the form of erythema and edema in all test animals. One animal exhibited medium-grade erythema and three animals showed scarcely perceptible skin irritations.

The challenge with 2-ethyl-2-oxazoline (5% in vehicle) produced very mild to prominent erythema on the right rear flanks of 11 test animals 30 hours after application. In 8 of these animals, it was associated with scarcely perceptible edema. The remaining 9 animals and the 10 animals of the control group showed no symptoms of irritation on the skin 30 hours after application. 54 hr after the start of the induction, 5 animals still showed very mild to distinct erythema and scarcely perceptible edema. The skin reactions were associated with dryness of the skin in 3 animals. In 15 test animals and all control animals, no signs of irritation were observed at these observation times.

The patch with the vehicle on the right front flank resulted in no skin reactions of any animal of the test or control group.

The following table summarizes the results of the challenge:

Evaluation Times	Number of Animals with Skin Reaction			
	30 Hours After Administration		54 Hours After Administration	
	5% Test Substance E / O	Vehicle E / O	5% Test Substance E / O	Vehicle E / O
Control group (n = 10)	0 / 0	0 / 0	0 / 0	0 / 0
Test group (n = 20)	11 / 8	0 / 0	5 / 5	0 / 0

n = number of animals used
E = erythema and scabbing
O = edema

Thus, 2-ethoxy-2-oxazoline showed a sensitizing action on the guinea pig skin under the test conditions described.

hüls	Prüfinstitut für Toxikologie 45764 Marl	Phone No.: 02365/494890

Final Report

No. AH-94/0124

Degussa-Hüls AG – REG No.
94 0250 DGT

Test of Acute Skin-Irritant Action of

2-Ethyl-2-oxazoline

on the Rabbit

The undersigned hereby declares that the tests described in the following report were conducted under his supervision according to good laboratory practice (GLP), in accordance with Appendix 1 to the Chemical Law of Aug. 1, 1994 (OECD – Principles of Good Laboratory Practice (GLP) of Feb. 4, 1983) and the results completely report the course of the study.

Study Director	Dr. Mürmann	[Signature]	Date	Sept. 27, 94

The final report comprises 19 pages.

Summary

The test for acute skin irritation on the rabbit with 2-ethyl-2-oxazoline was conducted on one animal at an exposure time of 4 hr and one animal at an exposure time of 3 min. The test showed that dermal application of the liquid test substance semi-occlusively for 4 hours of exposure resulted in very severe erythema with deep injuries and severe edema 30-60 min to 24 hr after patch removal. Further, the skin was brown-black in color, hardened, parchment-like and necrotic. The edge of the application area was bloody 1 hr after patch removal, and, after 24 hr, severe subdermal hemorrhaging was observed at this area. The animal was killed after the 24 hr evaluation because of the severe skin injuries.

The application of the test substance for a 3-minute exposure time (open patch) resulted in a moderate to severe erythema associated with severe edema (swelling more than 1 mm and beyond the exposure area) after 1 hour to 72 hr on the skin of one rabbit. Further, the skin showed brownish-red discoloration and severe subdermal hemorrhaging up to 48 hr after application. After 24 hr, the skin in the application area was dry and hardened. After 48 hr, the hardened skin became undulated. Six days after treatment, no erythema or edema were observed. A thick, chapped scaly crust had formed in the area of application. The edge of the treated area was partially bloody-red colored. After 8 to 20 days, the scaly crust slowly detached itself to form scales and scars. On the 24th day after application, bristly hairs started to grow in the area of application.

Both the 4-hour exposure time under a semi-occlusive patch and the 3-minute open application of the test substance resulted in irreversible skin damage in the area of application.

Hüls AG
Prüfinstitut für Toxikologie
Final Report AH-94/0124

The following values were determined from the numerically evaluated individual findings at the observation time of 24 hr after the end of the exposure time:

Exposure Time 4 Hr	Animal 1
Erythema and scabbing	4.0
Edema	4.0

The following mean values were calculated from the numerically evaluated individual findings at the observation times of 24, 48 and 72 hr after the end of the exposure time:

Exposure Time 4 Hr	Animal 2
Erythema and scabbing	3.0
Edema	4.0